IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Geila Rozen et al.	Confirmation No.: 3116
Application No.: 10/591,734	Patent No.: 7,919,526 B2
Filing Date: May 1, 2007	Patent Date: April 5, 2011
For: STRUCTURED TRIGLYCERIDES AND EMULSIONS COMPRISING SAME	Attorney Docket No.: 85189-9500

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 CFR § 1.322

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

It is requested that a Certificate of Correction be issued in connection with the above-identified patent correcting the errors listed on the accompanying Form PTO-1050. The corrections requested are as follows.

On the Title page, before Item (51), insert the following:

-- **Related U.S. Application Data**

(60) Provisional application no. 60/549,550, filed Mar. 4, 2004 --

Support for this change appears on the executed Declaration filed May 1, 2007.

In column 28, line 18 (claim 18, line 11), change "C_{20}-C_{12}" to -- C_{20}-C_{22} --.

Support for this change appears in application claim 31.

This request is being made pursuant to 37 CFR § 1.322 to correct errors that are clerical or typographical in nature and appear to have been made by the Office during the printing of the patent. Therefore, no fee is believed to be due for this request. Should any fees be required, however, please charge such fees to Winston & Strawn LLP Deposit Account No. 50-1814.

Please issue a Certificate of Correction in due course.

Respectfully submitted,

Date: April 13, 2011

Allan A. Fanucci, Reg. No. 30,256

WINSTON & STRAWN LLP
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212-294-3311

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,919,526 B2

APPLICATION NO. : 10/591,734

DATED: : April 5, 2011

INVENTOR(S) : Rozen et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Page:

Before Item (51), insert the following:

-- **Related U.S. Application Data**

(60) Provisional application no. 60/549,550, filed Mar. 4, 2004 --

Column 28:

Line 18 (claim 18, line 11), change "C_{20}-C_{12}" to -- C_{20}-C_{22} --.

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(12) **United States Patent**
Rozen et al.

(10) **Patent No.: US 7,919,526 B2**
(45) **Date of Patent: Apr. 5, 2011**

(54) **STRUCTURED TRIGLYCERIDES AND EMULSIONS COMPRISING SAME**

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(73) Assignee: **HTL High-Tech Lipids Ltd.**, D.N. Misgav (IL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 965 days.

(21) Appl. No.: **10/591,734**

(22) PCT Filed: **Mar. 3, 2005**

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§ 371 (c)(1),
(2), (4) Date: **May 1, 2007**

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PCT Pub. Date: **Sep. 15, 2005**

(65) **Prior Publication Data**

US 2007/0281993 A1 Dec. 6, 2007

(51) **Int. Cl.**
A61K 31/355 (2006.01)

(52) **U.S. Cl.** **514/458**; 514/560; 554/227

(58) **Field of Classification Search** 514/458, 514/560; 554/227

See application file for complete search history.

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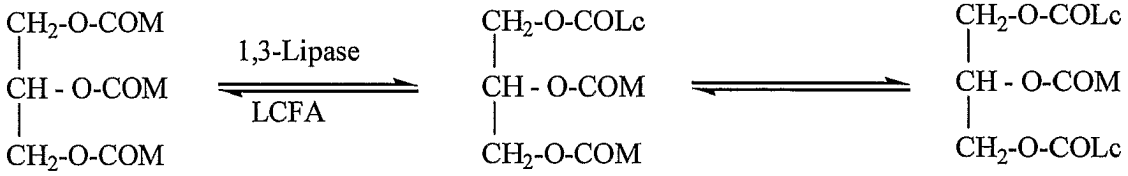
(57) **ABSTRACT**

The present invention relates to structured triglyceride, to parental nutrition emulsions comprising same, and use thereof. In particular, the invention relates to structured triglycerides comprising at least one medium chain C_6-C_{12} fatty acid and at least one fatty acid selected from the group consisting of long chain C_{14}-C_{18} or very long chain C_{20}-C_{22} fatty acids, preferably each fatty acid is present in a predetermined position of the glycerol backbone. The parenteral nutrition emulsions are particularly useful for nourishing preterm- and term-infants, children, critically ill patients, and cancer patients.

41 Claims, 3 Drawing Sheets



Related U.S. Application Data

(60) Provisional application no. 60/549,550 filed Mar. 4, 2004

7. The parenteral nutrition emulsion composition according to claim 1, comprising from about 4.5 to about 5.5% by weight C_{20}-C_{22} fatty acids based on the weight of total fatty acids.

8. The parenteral nutrition emulsion composition according to claim 1, wherein the ω-6 fatty acids and the ω-3 fatty acids are present in a ratio of about 2:1 to about 1.5:1.

9. The parenteral nutrition emulsion composition according to claim 1, wherein the structured triglyceride constitutes from about 10 to about 40% (w/v) of the composition.

10. The parenteral nutrition emulsion composition according to claim 1, wherein the structured triglyceride constitutes from about 20 to about 25% (w/v) of the composition.

11. The parenteral nutrition emulsion composition according to claim 1, wherein a droplet size of said emulsion is lower than about 0.22 μm.

12. The parenteral nutrition emulsion composition according to claim 1, further comprising tocopherol.

13. The parenteral nutrition emulsion according to claim 12, wherein the tocopherol is alpha tocopherol.

14. The parenteral nutrition emulsion according to claim 1, further comprising an emulsifier.

15. The parenteral nutrition emulsion according to claim 1, further comprising at least one component selected from the group consisting of surfactants, carbohydrates, vitamins, amino acids, trace minerals, osmolality modifiers and water.

16. The parenteral nutrition composition according to claim 1 comprising:

(a) about 20% (w/v) structured triglycerides comprising:
- about 40-50% by weight C_6-C_{12} fatty acids based on the weight of total fatty acids, wherein the C_6-C_{12} fatty acids comprise 0-5% caproic acid, 20-30% caprylic acid, 10-30% capric acid, and 0-5% lauric acid by weight based on the weight of total fatty acids;
- about 35-55% by weight C_{14}-C_{18} fatty acids based on the weight of total fatty acids, wherein the C_{14}-C_{18} fatty acids comprise 0-5% mystiric acid, 5-30% palmitic acid, 0-5% palmitoleic acid, 0-5% stearic acid, 10-30% oleic acid, 10-30% linoleic acid, and 5-15% alpha linolenic acid by weight based on the weight of total fatty acids; and
- about 1-10% C_{20}-C_{22} by weight fatty acids based on the weight of total fatty acids, wherein the C_{20}-C_{22} fatty acids comprise 1-5% AA, 0-5% EPA, and 1-5% DHA by weight based on the weight of total fatty acids, wherein the ratio of ω-6 to ω-3 fatty acids is about 1:1 to about 2:1;

(b) 1.2% (w/v) phospholipids;

(c) 1.8-2.0 mg/1 g of fatty acids alpha tocopherol;

(d) 0-25 g/L glycerin; and

(e) water.

17. The parenteral nutrition emulsion composition according to claim 16 comprising:

(a) about 20% (w/v) structured triglycerides comprising:
- about 45% by weight C_6-C_{12} fatty acids based on the weight of total fatty acids, wherein the C_6-C_{12} fatty acids comprise 2.5% caproic acid, 30% caprylic acid, 10% capric acid, and 2.5% lauric acid by weight based on the weight of total fatty acids;
- about 50% by weight C_{14}-C_{18} fatty acids based on the weight of total fatty acids, wherein the C_{14}-C_{18} fatty acids comprise 10% palmitic acid, 2.5% stearic acid, 15% oleic acid, 16% linoleic acid, and 7% alpha linolenic acid by weight based on the weight of total fatty acids; and
- about 5% by weight C_{20}-C_{22} fatty acids based on the weight of total fatty acids, wherein the C_{20}-C_{22} fatty acids comprise 1.5% AA, 1.5% EPA, and 1.5% DHA by weight based on the weight of total fatty acids, wherein the ratio of ω-6 to ω-3 fatty acids is 1.75;

(b) about 1.2% (w/v) phospholipids;

(c) about 1.8 mg/1 g of fatty acids alpha tocopherol;

(d) about 10-25 g/L glycerin; and

(e) water.

18. A parenteral nutrition emulsion composition comprising a structured triglyceride, the structured triglyceride comprising a glycerol backbone having three fatty acid residues esterified thereto, wherein at least one fatty acid residue is selected from the group consisting of C_6-C_{12} fatty acids and active derivatives thereof in the internal position of the triglyceride backbone, and at least one fatty acid residue is selected from the group consisting of C_{14}-C_{18} fatty acids, C_{20}-C_{22} fatty acids, and active derivatives thereof in an external position of the triglyceride backbone, wherein the C_{14}-C_{18} fatty acids and the C_{20}-C_{12} fatty acids include ω-3 and ω-6 fatty acids, optionally in combination with ω-9 fatty acids, wherein the ω-6 fatty acids and the ω-3 fatty acids are present in the emulsion composition in a ratio of about 7:1 to about 1:1, and wherein the emulsion composition has a droplet size of less than about 1 μm. C_{20}-C_{22}

19. The parenteral nutrition emulsion composition according to claim 18, comprising from about 9 to about 90% by weight C_6-C_{12} fatty acids based on the weight of total fatty acids.

20. The parenteral nutrition emulsion composition according to claim 18, comprising from about 40 to about 50% by weight C_6-C_{12} fatty acids based on the weight of total fatty acids.

21. The parenteral nutrition emulsion composition according to claim 18, comprising from about 9% to about 90% by weight C_{14}-C_{18} fatty acids based on the weight of total fatty acids.

22. The parenteral nutrition emulsion composition according to claim 18, comprising from about 35% to about 55% by weight C_{14}-C_{18} fatty acids based on the weight total fatty acids.

23. The parenteral nutrition emulsion composition according to claim 18, comprising from about 1% to about 10% by weight C_{20}-C_{22} fatty acids based on the weight of total fatty acids.

24. The parenteral nutrition emulsion composition according to claim 18, comprising from about 4.5% to about 5.5% by weight C_{20}-C_{22} fatty acids based on the weight of total fatty acids.

25. The parenteral nutrition emulsion composition according to claim 18, wherein the ω-6 fatty acids and the ω-3 fatty acids are present in a ratio of about 2:1 to about 1.5:1.

26. The parenteral nutrition emulsion composition according to claim 18, wherein the structured triglyceride constitutes from about 10 to about 40% (w/v) of the composition.

27. The parenteral nutrition emulsion composition according to claim 18, wherein the structured triglyceride constitutes from about 20 to about 25% (w/v) of the composition.

28. The parenteral nutrition emulsion composition according to claim 18, wherein a droplet size of said emulsion is lower than about 0.22 μm.

29. The parenteral nutrition emulsion composition according to claim 18, further comprising tocopherol.

30. The parenteral nutrition emulsion composition according to claim 29, wherein the tocopherol is alpha tocopherol.

31. The parenteral nutrition emulsion composition according to claim 18, further comprising an emulsifier.

32. The parenteral nutrition emulsion composition according to claim 18, further comprising at least one component